



May 3, 2023

COVID-19 Vaccine Updates

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PREP Act for Medical Countermeasures Against COVID-19

Health and Human Services (HHS) released a [fact sheet](#) about an upcoming amendment to the COVID-19 PREP Act declaration. This will be the eleventh amendment to the declaration and seeks to clarify issues around provider liability protections.

Key immunization changes under the upcoming amended declaration include:

- **Extending coverage for COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests.** PREP Act immunity from liability will be extended through December 2024 to pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (to those individuals three and over, consistent with other requirements), and COVID-19 tests, regardless of any USG agreement or emergency declaration.

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- **Extending coverage through December 2024 for Federal agreements.** This includes all activities related to the provision of COVID-19 countermeasures that are 1) provided based on a federal agreement (including the vaccines and treatments purchased and provided by the USG), or 2) directly conducted by the USG, including by Federal employees, contractors or volunteers.
- **Ending of coverage for certain activities.** Once products are no longer distributed under a USG agreement, PREP Act coverage will no longer extend to the following activities:
 - COVID-19 vaccination by non-traditional providers (e.g., recently retired providers and students); and
 - COVID-19 vaccinations across state lines by licensed providers and pharmacists and pharmacy interns.
- **Ending of coverage for routine childhood vaccinations.** Once there is no emergency in effect, PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians.

Some of the key features that will not change under the amended declaration include:

- **No immediate impact on USG-distributed COVID-19 countermeasures.** As noted above, the amended PREP Act declaration will not have any immediate impact on COVID-19 vaccines, treatments, and tests currently distributed by the USG—either now or when the COVID-19 PHE ends on May 11.

COVID-19 Vaccine Commercialization After May 11, 2023

The end of a public health emergency does not equate to the end of the current national vaccine distribution program or the availability of vaccine commercially. Commercialization is the transition of COVID-19 medical countermeasures, including vaccines, treatments, and test kits previously purchased by the U.S. Government (USG), to establish pathways of procurement, distribution, and payment by both public and private payers.

Commercialization will include:

- The transition from direct government purchases to public and private payers' purchases. Expected fall 2023.
- Upfront costs for providers who purchase COVID-19 vaccines.
- Vaccine costs will be covered by private/public insurance.
 - Will be covered by the Vaccines for Children (VFC) program.
 - **Medicare-** People with Medicare coverage will continue to have access to COVID-19 vaccinations without cost sharing.
 - **Medicaid-** As a result of the *American Rescue Plan Act of 2021 (ARPA)*, states must provide Medicaid and CHIP coverage without cost sharing for COVID-19 vaccinations through the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE. If the COVID-19 PHE ends as expected on May 11, 2023, this coverage requirement will end on September 30, 2024.
 - **Private Health Insurance-** Most forms of private health insurance will continue to cover COVID-19 vaccines furnished by an in-network health care provider without cost sharing. There may be a cost if using an out-of-network provider.

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Interim Clinical Considerations for Use of COVID-19 Vaccines

CDC has updated the [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#) to reflect the following changes in the mRNA COVID-19 vaccination schedule:

- At the time of initial vaccination, depending on vaccine product, children ages 6 months–4 years are recommended to receive 2 or 3 bivalent mRNA vaccine doses; children aged 5 years are recommended to receive 1 or 2 bivalent mRNA vaccine doses.
- People ages 6 years and older who are unvaccinated or previously received only monovalent vaccine doses are recommended to receive 1 bivalent mRNA vaccine dose.
- People ages 65 years and older may receive 1 additional bivalent mRNA vaccine dose.

Revision of the mRNA COVID-19 vaccination schedule for people who are [moderately or severely immunocompromised](#) is as follows:

- At the time of initial vaccination, people ages 6 months and older are recommended to receive 3 bivalent mRNA doses.
- People ages 6 months and older who previously received only monovalent doses are recommended to receive 1 or 2 bivalent mRNA vaccine doses, depending on age and vaccine product.
- People who previously received a bivalent mRNA vaccine dose(s) have the option to receive 1 or more additional bivalent mRNA doses.

[April 19, 2023, ACIP Meeting: COVID-19 Vaccine Program Updates Slides](#)

Update Inventories in I-CARE

Inventory Management and Reporting in VaccineFinder and I-CARE

We continue to encourage you to properly manage and report your inventory:

- Practice first in/first out inventory management.
 - Store older vaccines to the front of the refrigerator or freezer unit.
 - Dispose of any expired vaccine according to state and local regulations.
- Update/zero out inventory in VaccineFinder and I-CARE
 - Providers should [properly dispose of expired inventory](#) per the enrollment agreement.
 - Record retention is required for a minimum of three years.
 - **Providers no longer participating in COVID-19 vaccination must zero out all inventory.**
 - If you no longer wish to participate in the COVID-19 vaccine program, please also notify dph.immunizations@illinois.gov and dph.vaccines@illinois.gov to complete the unenrollment process.

I-CARE Inventory Removal

Several types of vaccines will be eliminated from the I-CARE inventories the week of May 8, 2023. **If you have additional data to enter, please complete it before May 8, 2023.** For more information see SIREN: Coronavirus (COVID-19) Vaccine Disposal and Reporting.

These vaccines will include:

- All monovalent Pfizer-BioNTech COVID-19 vaccines. All have been deauthorized.

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- All monovalent Moderna COVID-19 vaccines. All have been deauthorized.
- All Janssen / Johnson & Johnson COVID-19 vaccines. All will be expired by May 6, 2023, and should be removed from physical inventory and properly disposed of at that time.
- The Novavax COVID-19 vaccines that were in 10-dose vials (Unit of Sale NDC 80631-100-10). All have expired by April 30, 2023.
 - NOTE: This product was replaced by a new Unit of Sale NDC 80631-102-10. The new product is available in a 5-dose vial.

Preventing Administration of Expired Vaccines

Administering expired vaccines continues to be a reported vaccine administration error. However, this error can be prevented by following these suggestions:

- Providers should check the expiration dates of vaccine in their storage unit weekly. Check vaccine expiration dates using the manufacturers' online expiry checking tools:
 - [Moderna Vial Expiration Checker](#)
 - [Pfizer-BioNTech COVID-19 Vaccine Expiry Checker](#)
 - [Novavax Expiry Date Checker](#)
 - [Janssen Expiry Checker](#)
- Remove expired vaccine from storage units and discard according to state and local regulations.
- Label vaccines with Beyond-Use labels indicating the date and time of expiration.
- Check the expiration date prior to preparing or administering the vaccine. NEVER administer expired vaccine.
- If expired vaccine is inadvertently administered:
 - Review guidance on the CDC website: [Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates | CDC.](#)
 - Report vaccine administration errors to the [Vaccine Adverse Event Reporting System.](#)
- For persons seeking vaccine who have not completed a primary series, see [Clinical Guidance for COVID-19 Vaccination | CDC.](#)

V-Safe System

V-safe was developed specifically for COVID-19 vaccines and has been an essential component of pandemic vaccine safety monitoring systems that have successfully and comprehensively characterized the safety of the COVID-19 vaccines used in the United States. At this point in the program, very little new data are being reported to the [v-safe system](#), and new enrollments will come to a close.

Since its launch in December 2020, 10.1 million v-safe participants completed more than 151 million health surveys about their experiences following COVID-19 vaccination, and v-safe data have been included in more than 20 scientific publications.

Please note the following important details for v-safe users:

- After May 19, 2023, those who had enrolled and participated in v-safe for COVID-19 vaccines will be unable to add new COVID-19 vaccine doses to their account.
- Health check-ins (and follow-up calls, if needed) for any doses added before May 19 will continue until June 30, 2023.

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- V-safe participants will continue to have access to their account to review previous entries and to complete remaining health check-ins until June 30, 2023.

CDC will continue to monitor COVID-19 vaccines through its other established vaccine safety monitoring systems. V-safe users or others who get vaccinated can report any possible health problems or adverse events following vaccination to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

CDC is developing a new version of [v-safe](#), launching later this year, which will allow users to share their post-vaccination experiences with new vaccines. COVID-19 vaccines are [safe](#) and [effective](#). CDC continues to recommend that everyone ages six months and older should stay [up to date](#) with all COVID-19 vaccines, including an updated vaccine when eligible.

COVID-19 Vaccine Availability

The following COVID-19 vaccines are available for ordering.

Product	Unit of Sale NDC
Moderna	
12 years of age and older at 0.5mL 6 through 11 years of age at 0.25mL 6 months through 5 years of age (Doses 1 and 2 only) at 0.25 mL	80777-0282-99
6 months through 5 years of age (Dose 3 only) at 0.2 mL	80777-0283-99
Pfizer	
12 years of age and older	59267-0304-2
5 through 11 years of age	59267-0565-2
6 months through 4 years of age	59267-0609-2
12 years of age and older single dose vial	59267-1404-2
Novavax (non-mRNA, monovalent)	
12 years of age and over	80631-0100-10

Release of COVID-19 Vaccination Mapping Tool

The CDC released a new [COVID-19 Vaccination Mapping Tool](#) via CDC's COVIDVaxView. This geographic information system (GIS) tool allows jurisdictions and other partners to use web maps, applications, and services to inform planning for vaccine-related activities. This tool includes local-level indicators that contribute to vaccine confidence and vaccination coverage, visualize data for vulnerable populations, identify community resources and barriers, and connect community stakeholders.

Bivalent Coverage in the U.S.

As of April 13, 2023, only 16.7% of the total U.S. population has received a bivalent COVID-19 vaccine. Of those, 20.2% are adults 18 years and older. Bivalent Vaccine Coverage is lower among individuals:

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- Who identify as Black, non-Hispanic, Hispanic/Latino, and Native Hawaiian or Other Pacific Islanders
- With lower income
- Without health insurance

COVID-19 vaccines continue to be the most effective tool in preventing serious illness, hospitalization, and death from COVID-19. The updated bivalent COVID-19 vaccines are not yet equitable, and coverage remains low. With simpler recommendations that are easier to communicate this may improve vaccine coverage rates. [CDC COVID Data Tracker: Vaccinations in the US](#)

Patient Education Resources

The American Public Health Association (APHA) has **new communications materials** to help you educate your patients about:

- Who is at increased risk for severe illness from COVID
- The availability of COVID treatments
- The importance of getting treated early

Developed in partnership with the U.S. Department of Health and Human Service's COVID-19 Public Education Campaign, [We Can Do This](#), the materials include handouts, posters, talking points and social media shareables, in both English and Spanish. The information comes from the U.S. Centers for Disease Control and Prevention and has been culturally tailored by the *We Can Do This* campaign's team of multicultural experts.

Social Media Resources

Social media resources have been developed to help you share information on the updated bivalent COVID-19 booster. Sample content and graphics are available for Twitter, Facebook, or Instagram (See below). Please note that URLs do not become active links when used on Instagram. To direct Instagram users to an external website, add the link to your bio and let your followers know to click the link in your bio for more information. Graphics displayed below are available to be copied for use in a post.



Updated Booster Recommendations

Are you the personal caregiver for someone over 65? Older adults are more likely to get very sick from COVID-19. Share with them the benefits of getting an updated COVID-19 booster to reduce severe illness, hospitalization, and death. Learn more: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html?s_cid=eb_sovc0008



Updated Booster Recommendations- Immunocompromised

If you have a weakened immune system, you are at higher risk of severe illness, hospitalization, and death from COVID-19. The added protection an updated COVID-19 vaccine provides may help lower your risk. Learn more:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#when-you-can-get-booster?s_cid=eb_sovc0010



CDC Booster Tool

Need answers on updated COVID-19 booster eligibility, timing, and available vaccines? CDC's booster tool is an easy-to-use guide that can give you the information you need. Learn more: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#when-you-can-get-booster?s_cid=eb_sovc0010

Illinois Residents Can Download Their Immunization Records

Illinois Department of Public Health's (IDPH) online immunization portal, Vax Verify, allows Illinois residents to access their immunization record. Refer to this article for user tips.

<https://www.helpguidethrive.org/post/how-illinois-residents-can-download-their-immunization-recordsnbs>

Resources

Public Health Emergency (PHE) End Date

- [CMS.gov: Current Emergencies](#)
- [CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency](#)
- [Coronavirus waivers & flexibilities](#)
- [FDA FAQs: What happens to EUAs when a public health emergency ends?](#)
- [Unwinding and Returning to Regular Operations after COVID-19](#)

Commercialization

- [Commercialization of COVID-19 Medical Countermeasures \(FAQ\)](#)
- [Working with partners to transition COVID-19 medical products to the commercial markets \(Blog\)](#)
- [Medical Countermeasure Commercialization | ASPR TRACIE](#)

Morbidity and Mortality Weekly Reports (MMWR)

- [COVID-19 Vaccination Coverage and Demographic Characteristics of Infants and Children Aged 6 Months–4 Years — United States, June 20–December 31, 2022](#)
- [COVID-19 Bivalent Booster Vaccination Coverage and Intent to Receive Booster Vaccination Among Adolescents and Adults — United States, November–December 2022](#)
- [Preliminary Estimates of Effectiveness of Monovalent mRNA Vaccines in Preventing Symptomatic SARS-CoV-2 Infection Among Children Aged 3–5 Years — Increasing Community Access to Testing Program, United States, July 2022–February 2023](#)

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- [Use of COVIDTests.gov At-Home Test Kits Among Adults in a National Household Probability Sample, United States, 2022.](#)
- [The Association of Reported Experiences of Racial and Ethnic Discrimination in Health Care with COVID-19 Vaccination Status and Intent — United States, April 22, 2021–November 26, 2022](#)

Updated Moderna COVID-19 Vaccine Resources

- [Moderna COVID-19 Vaccine Fact Sheet: Recipients and Caregivers](#)
- [Moderna COVID-19 Vaccine Fact Sheet: Healthcare Providers](#)
- [Moderna Dear Healthcare Provider Letter](#)

Updated Pfizer-BioNTech COVID-19 Vaccine Resources

- [Pfizer COVID-19 Vaccine Fact Sheet: Recipients and Caregivers](#)
- [Pfizer-BioNTech COVID-19 Vaccine Fact Sheet: Healthcare Providers](#)
- [Pfizer and BioNTech COVID-19 Vaccines Healthcare Provider Website](#)
- [Pfizer Medical Information Website](#)

Webinars

- Recorded Webinar and Slides: IL Chapter American Academy of Pediatrics: [Simplified COVID-19 Schedules & More](#)
- Recorded Webinar: [Evaluating and Supporting Children and Adolescents Presenting with Post-COVID Conditions](#)
- Clinical Outreach and Communication Activity (COCA) Call/Webinar – Title: Updated Recommendations for COVID-19 Vaccine Use. Thursday, May 11, 2023, 1-2:00 PM CT (2pm ET) [Webinar Link](#)

Medical Training and Office Hours

Pfizer Live Webinars

Pfizer Medical Affairs is conducting **live webinars** for all healthcare providers for a limited time. Please visit the [Pfizer website](#) for the latest training schedule. Key updates include:

- CDC no longer recommends the monovalent Pfizer-BioNTech COVID-19 Vaccine.
- EUA Fact Sheets have been consolidated to include all age groups.
- Updated EUA Fact Sheet dosing schedule for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5).
- Dosing schedule no longer refers to “primary series” or “booster dose(s).”
- Includes guidance for certain individuals eligible to receive “additional dose(s).”

Moderna Interactive Office Hours

Moderna is offering a series of interactive office hours focusing on simplified dosing schedules for Moderna COVID-19 vaccine, bivalent, and other updates. [Register](#) for an upcoming session.

Novavax Webinars

Novavax hosts office hours each week. [Register](#) for an upcoming session.

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